ENDOCRINE DISRUPTING CHEMICALS (EDCS) MID-CYCLE REVIEW SUBCOMMITTEE

Conference Call Summary
Wednesday, October 17, 2007
3:00 p.m. – 5:00 p.m. Eastern Time

Welcome

Dr. Deborah Swackhamer, University of Minnesota, Subcommittee Chair

Before the meeting was called to order, Mr. Adam Sarvana requested a copy of the draft report. Ms. Heather Drumm, the Designated Federal Officer (DFO) for the Endocrine Disrupting Chemicals (EDCs) Mid-Cycle Review Subcommittee, said that she would e-mail a copy to him.

Dr. Deborah Swackhamer, Chair of the EDCs Mid-Cycle Review Subcommittee, welcomed the Subcommittee members to the conference call and thanked them for participating in this review. Dr. Swackhamer explained that the objective of the call was to refine the draft report written after the face-to-face meeting held on September 18, 2007, in Arlington, Virginia.

Dr. Swackhamer asked Ms. Drumm to discuss the administrative procedures for the call.

Administrative Procedures

Ms. Heather Drumm, U.S. Environmental Protection Agency (EPA)/ORD, Designated Federal Officer

Ms. Drumm thanked the Subcommittee members for their participation in this mid-cycle review. She then reviewed the Federal Advisory Committee Act (FACA) procedures that are required for all Board of Scientific Counselors (BOSC) Subcommittee meetings. As the DFO for the Subcommittee, Ms. Drumm serves as the liaison between the Subcommittee and ORD. She stated that it is her responsibility as the DFO to ensure that the Subcommittee's conference calls and meetings comply with all FACA rules.

The BOSC is a Federal Advisory Committee that provides independent, scientific peer review and advice to EPA's Office of Research and Development (ORD), and as such, is subject to the rules and requirements of FACA. The EDCs Mid-Cycle Review Subcommittee was established by the BOSC to review the progress made by the EDCs Program since the program review that was conducted by the BOSC in December 2004. All meetings and conference calls involving substantive issues—whether in person, by phone, or by e-mail—that include one-half or more of the Subcommittee members must be open to the public, and a notice must be placed in the *Federal Register* at least 15 days prior to the call or meeting. The Subcommittee Chair and DFO

must be present at all conference calls and meetings. All advisory committee documents are made available to the public. Ms. Drumm reported that no requests for public comment were submitted prior to the call, but the agenda allows time for public comment at 4:00 p.m. She will call for public comments at that time, and each comment should be limited to 3 minutes.

This is the third meeting for the EDCs Mid-Cycle Review Subcommittee. The first conference call was held on August 21, 2007, and a second conference call scheduled for September 14, 2007, was cancelled. A face-to-face meeting was held on September 18, 2007, in Arlington, Virginia. This call is a followup to that meeting to allow Subcommittee members to discuss the draft report that resulted from that meeting. Another conference call is scheduled for November 6, 2007. At the end of today's call, it will be determined if that call is needed.

Subcommittee Discussion, Draft Report
Dr. Deborah Swackhamer, University of Minnesota, Subcommittee Chair

Dr. Swackhamer asked if Dr. Stephen Safe was on the call and there was no reply. Ms. Drumm said she would send him an e-mail to remind him about the call.

Dr. Swackhamer explained that she compiled the comments from all the Subcommittee members to create the draft report. She did not want to risk losing the intent of any Subcommittee member, so she did not delete any material. The purpose of today's call is to come to an agreement on the overall construct of the report and to discuss how best to integrate the different responses. Dr. Glen Van Der Kraak stated that he liked the format of the report; however, some Subcommittee members included ratings in their sections such as Exceeds Expectations and Exceptional, while others did not. What is the correct format? Dr. Swackhamer explained that the Subcommittee's charge was to provide a rating for the overall program. She suggested omitting the ratings in Dr. Boyd's text but retaining the examples associated with the ratings. Dr. Glen Boyd explained that he had used the ratings to organize his thoughts, but did not intend for the final text to include them. Ms. Drumm mentioned that the Subcommittee members might find it helpful to review past mid-cycle review reports, which are posted on the BOSC Web Site. Ms. Drumm agreed to send the Subcommittee members the link to the site. Dr. Swackhamer proposed that the report be condensed into three sections: summary, introduction, and response to the charge questions, which would include a subsection for each question. The other Subcommittee members agreed with this suggestion. Dr. Swackhamer said that she would edit the text accordingly.

<u>Introduction</u>

Dr. Swackhamer asked the Subcommittee members if there was anything missing from the Introduction. Dr. Van Der Kraak suggested adding text to the second paragraph indicating that the EDCs Research Program had, in addition to the response letter to the BOSC, drafted a Progress Report in response to the 2004 BOSC review. Dr. Swackhamer agreed to add the suggested text.

Charge Question 1 – How responsive has the Endocrine Disruptors Research Program been to the recommendations from the 2004 BOSC program review?

Dr. Swackhamer stated that she liked Dr. Safe's approach of discussing each Long-Term Goal (LTG) in detail. She had written the opening paragraph and would like it to remain if the others were in agreement. She noted that Dr. Boyd's text would need to be edited to reflect that each LTG was discussed in the response. She thought it would be helpful to include examples where the Program had and had not met its goals. Dr. Boyd suggested that the recommendations currently listed under the LTGs be moved to Charge Question 4. He gave an example from LTG 1:

"It is recommended that the EDC Research Program continue and expand these interactions and also consider other relevant partners from industry and government in this country and abroad (e.g. ICVAM). In addition, EPA and other regulatory agencies (national and international) should also consider more harmonization regarding the results of EDC scientific studies and their applications for risk assessment. Long range planning may want to incorporate a systems biology approach which addresses critical end-points since this type of integrated assay can be highly predictive for evaluating different compounds. Pharmaceutical companies increasingly rely on the predictive capabilities of systems biology."

Dr. Van Der Kraak mentioned that he thought the section implied that the Computational Toxicology Program had evolved from the EDCs Program; he did not know if this was correct. Dr. Swackhamer asked Dr. Francis to address this issue. Dr. Francis clarified that the Computational Toxicology Program began in 2002 with a focus on endocrine-mediated issues, but did not evolve out of the EDCs Research Program. Dr. Van Der Kraak suggested editing the text to reflect this. Dr. Swackhamer noted that examples of the work performed to address each LTG were included in the LTG sections, but also in the subsequent text written by Dr. Boyd. She suggested including all the examples in the LTG sections. Dr. Boyd thought this was a good idea, but noted that the tone in the LTG 1 discussion was very positive. In his examples, he had noted that risk management was not being addressed; thus, the tone should be changed to reflect this.

Dr. Swackhamer summarized the approach she envisioned, which was to refine the discussion under the LTGs, balance it out to make sure all the important topics were included, and integrate Dr. Boyd's examples into the LTG discussions. Dr. Boyd added that the recommendations should be moved to Charge Question 4. Dr. Van Der Kraak pointed out that the sections under each LTG should be similar in length. The longer discussion for LTG 1 gives the impression that LTG 1 is more important than the other LTGs. Dr. Swackhamer agreed. Dr. Van Der Kraak noted that a number of issues would fit under more than one LTG. Genomics is one example; EPA has taken a leadership role in this field. Dr. Van Der Kraak commended EPA for its innovative approaches to increasing the Agency's research base in the face of reduced funding. He suggested recognizing more positively the significant leveraging done with the STAR Program, despite the fact that funding for the STAR Program has been eliminated. Dr. Boyd stated that the actions taken by the EDCs Program in response to the BOSC program review recommendations should be made clear in the introduction. Did they take action? Or did they give a valid reason for not taking action? Dr. Swackhamer agreed that was an important

distinction and said she would make this clear in the introduction text. Dr. Van Der Kraak mentioned that Dr. Boyd's rating of Not Satisfactory for risk management issues seemed a little harsh. The Program has limited resources and made a strategic decision to focus on certain elements of LTG 1; it is better to do a few things well than to do many things poorly. Dr. Boyd agreed, but noted that LTG 1 currently lists risk management as an area of focus. Dr. Boyd suggested recommending that LTG 1 be rewritten to reflect that risk management currently is not being addressed. Dr. Swackhamer suggested using the paragraph that starts, "There was a previous effort…," omitting the rating, and inserting a second paragraph to add some context. Drs. Boyd and Van Der Kraak agreed. Dr. Van Der Kraak suggested also adding a description of what is missing from the risk management side, possibly including an example of how risk management would fit into the Program. Dr. Boyd said that he could write that text. Dr. Swackhamer summarized the changes to be made:

- ✧ The ratings will be removed from Dr. Boyd's text and the examples will be integrated into the LTG discussions. Edits will be made as needed to avoid redundancy.

- ✧ The LTG discussions and examples will be edited to achieve more balance.

- ✧ The recommendations in the LTG 1 discussion will be moved to the response to Charge Question 4.

- ✧ The first paragraph will be edited to more clearly define the different types of response (e.g., taking action, giving a valid reason for not taking action, etc.).

- ✧ Any issues that address more than one LTG will be included in the first paragraph.

Drs. Boyd and Van Der Kraak agreed with these changes.

Dr. Swackhamer proposed that each Subcommittee member be responsible for one or two sections of the report. She asked Dr. Van Der Kraak to take Charge Question 1 and he agreed to do so.

<u>Charge Question 2 – To what extent does the updated draft MYP provide a coherent framework and rationale for addressing priority research needs?</u>

Dr. Swackhamer suggested removing the second paragraph and making minor edits to the remaining text. Drs. Boyd and Van Der Kraak agreed. Dr. Swackhamer asked if they had any other comments on this section. Dr. Boyd suggested moving the sentence, "The updated draft MYP highlights the focus of EPA's contributions and emphasizes the contributions that EPA can make based on its strengths." to the beginning of the section to better highlight it. Dr. Van Der Kraak asked the others how they interpreted Charge Question 2. Should they address the specifics of the MYP, such as which goals have been achieved and which have not? Dr. Swackhamer interpreted the question as asking whether the MYP was an appropriate roadmap for the Program. Dr. Van Der Kraak suggested adding text explaining that much progress has been made and that the Program is on the right track. Dr. Swackhamer agreed to this suggestion and volunteered to make the edits to Charge Question 2.

Charge Question 3 – Are there performance metrics the Endocrine Disruptors Research Program should be using in addition to the current indicators (e.g., quality and impact of ORD publications, timeliness of completing goals) for regularly assessing research progress?

Dr. Swackhamer suggested removing the second paragraph because the points made there were captured in other text. She suggested moving the first paragraph to the end. The opening sentence would then be, "The performance metrics used to quantify the impact of EPA's EDCs Research Program were interesting and, using multiple criteria, clearly demonstrated the high quality of the research relative to other publications in the field." The section should move from the more obvious metrics to the more difficult ones.

Dr. Van Der Kraak agreed that this would be a good approach. He noted that he was a little concerned with one of the metrics currently used by the Program. The current method of bibliometric analysis appeared to include STAR grantees and count their publications toward the Program's publications regardless of whether or not those publications were funded by EPA. Dr. Swackhamer asked Dr. Francis for clarification. Dr. Francis explained that the bibliometric analysis did include both intramural and extramural research; for this reason, at times, other research would be included in the analysis. The EDCs Research Program is working to further integrate its intramural and extramural research, so while the Program leadership recognizes the limitations to this type of analysis, it was ultimately decided that this was the best approach. Dr. Swackhamer suggested acknowledging that the bibliometric analysis includes STAR grantees as well as EPA researchers. Dr. Van Der Kraak agreed with this approach and added that universities struggle with these same types of issues. He suggested adding a metric on the number of people serving on journal editorial boards. Dr. Swackhamer agreed with this suggestion and mentioned that the number of people serving on advisory boards could be another measure.

Public Comments
Ms. Heather Drumm, DFO, EPA/ORD

At 4:00 p.m., Ms. Drumm called for public comments. There were no comments offered.

Subcommittee Discussion, Draft Report, Next Steps
Dr. Deborah Swackhamer, University of Minnesota, Subcommittee Chair

Dr. Swackhamer stated that she had received an e-mail from Dr. Safe, who apologized for not being able to participate in the call due to unforeseen circumstances.

Dr. Swackhamer asked if the other Subcommittee members agreed with Dr. Safe's metric suggestions. She pointed out Dr. Boyd's suggestion to tie the measurements to budget constraints or full-time equivalents (FTEs) and asked if all were in agreement with that suggestion. Dr. Boyd mentioned that he had discussed the issue with Dr. Francis at the face-to-face meeting and she indicated that the Program had considered taking this type of approach, but had determined that it would be quite difficult. Dr. Van Der Kraak was concerned about this type of metric because there often is a long lag time between the research and the publishing of papers. Dr. Swackhamer said it sounded like they both had some reservations on that recommendation and asked if they

thought it should remain in the report. Dr. Boyd said that he was fine with leaving it in the report. Dr. Swackhamer said she agreed with the general idea but was hesitant about the specificity of the recommendation. Dr. Van Der Kraak noted that he agreed with the overall idea, but was concerned that they might be starting down a slippery slope, specifically because of the disconnect between funding and research results. A new program will be costly in the beginning when funds are spent to develop tools and technologies; at that point, the outcome per unit of cash will be very low. A mature program that has developed all of it tools and technologies can produce the research at a much lower cost per unit effort. Dr. Boyd said Dr. Van Der Kraak had a good point, but on the other hand, this type of analysis could help make EPA's work (and the lack of funding for it) more visible to the public and ultimately, benefit the Agency. Dr. Van Der Kraak agreed to leave it in the text, but suggested changing the tone to make it a softer recommendation. Dr. Swackhamer proposed adding text on the need to interpret impact factors and other metrics. Drs. Boyd and Van Der Kraak agreed with this. Dr. Boyd noted that the last paragraph in this section of the draft report, which he wrote, sounded like it was redundant in the context of the other comments. Dr. Swackhamer suggested leaving Dr. Boyd's paragraph as is and removing the redundancies from the other sections. She offered to be responsible for revising the response to Charge Question 3.

Charge Question 4 – What advice can the BOSC provide regarding the planned narrower focus and directions of the Endocrine Disruptors Research Program given its evolution and budget impacts?

Dr. Swackhamer stated that she wanted to make sure the Subcommittee members agreed on the contents of this section and asked if there were any comments. Dr. Van Der Kraak said he was concerned about whether the section adequately defined the narrower focus of the EDCs Research Program. Dr. Swackhamer mentioned that she thought Dr. Boyd had done a better job of addressing that issue than she had and suggested retaining the bullet points he had provided. Dr. Boyd explained that he made the suggestions about EPA expanding its work with other organizations and taking a leadership role because much of the work EPA has conducted can benefit other organizations and vice versa. Dr. Van Der Kraak agreed with this recommendation, but suggested editing the text to give it a more positive tone. He suggested first pointing out some of EPA's successful partnerships, such as its collaboration with other agencies and organizations on the topic of Concentrated Animal Feeding Operations (CAFOs). Dr. Boyd agreed with this suggestion. Dr. Swackhamer proposed starting that bullet point with the sentence on EPA taking a national leadership role. Dr. Boyd further suggested making that sentence a little more positive by pointing out areas in which EPA already had taken on a national leadership role. Dr. Swackhamer noted that the first and third bullets seemed very similar. Dr. Boyd agreed and said they could be consolidated. Dr. Van Der Kraak suggested adding text noting that the EDCs Research Program is addressing some very critical issues such as low-dose and mixture toxicology, and that these issues are being addressed despite budget cuts. Dr. Swackhamer agreed and suggested that the Subcommittee include a statement on the importance of the issues being addressed by the Program and on the need for continued funding. Drs. Boyd and Van Der Kraak agreed with this suggestion.

Dr. Swackhamer suggested adding text noting that while the toxicity side of the risk assessment paradigm needs attention, EPA should focus its efforts on exposure. Dr. Van Der Kraak thought

there were still significant needs in both areas. Dr. Boyd thought there was more of a need for exposure information, but deferred to Drs. Swackhamer and Van Der Kraak because of their expertise in this area. Dr. Swackhamer noted that Dr. Safe had listed suggestions that reflected his expertise as a toxicologist (e.g., understanding transgenerational affects, human susceptibilities, etc.). Dr. Swackhamer agreed that there is a great need for this type of information, but she thought that there may be other agencies that can or already do focus on those issues. She added that more people with different backgrounds are needed at the table to best answer this question. Dr. Van Der Kraak said that he thought the Subcommittee members could adequately address the question; he suggested reviewing each of the LTGs and determining if EPA's current focus will answer those critical questions. Dr. Swackhamer liked the idea of taking this type of systematic approach, but she had some concerns that the Program has very lofty goals; it is not clear if those goals can be reached if the realities of shrinking budgets are taken into account. Dr. Van Der Kraak noted that he thought the research described in the updated MYP would begin to answer those critical questions; this is an important step. Given the lack of resources available, the Subcommittee could suggest further partnering with other agencies and organizations. Dr. Swackhamer suggested that the Program could use cooperative agreements as one means to accomplish this. Dr. Van Der Kraak agreed that would be good advice. Dr. Boyd pointed out that he thought the Program was already doing what they were suggesting, in terms of focusing on the areas where it can have the most impact. He agreed with the comments made, but would add that EPA should aim to become more of a visible national leader; this will open the door to working with industry and will allow all the players to capitalize on what EPA has learned thus far. Dr. Swackhamer asked Dr. Francis if these types of recommendations were useful. Dr. Francis replied that it would be most helpful if the Subcommittee assessed whether or not the EDCs Research Program was on the right track. Suggestions for new research topics or greater emphasis in a specific topic area also would be welcome. Given this, Dr. Swackhamer proposed noting where the Program already was focused on the right topics and emphasizing the need to continue this work despite shrinking budgets. She did not see any huge gaps in the research plan and suggested reiterating that the important topics on which the Program is focusing should continue to be emphasized (e.g., low-dose, mixtures, transgenerational issues, etc.). Dr. Swackhamer agreed to be responsible for revising this section. Dr. Van Der Kraak offered to review her text and add anything that he thought was still needed.

<u>Charge Question 5 – Please rate the progress made by the Endocrine Disruptors Research Program in moving the program forward in response to the BOSC review of 2004 by assigning a qualitative score, i.e., exceptional, exceeds expectations, meets expectations, or not satisfactory.</u>

The Subcommittee members previously had agreed on an overall rating of Exceeds Expectations. The draft report currently includes a summary paragraph followed by bullet points detailing three different aspects of the evaluation (quality, speed, and success). Dr. Swackhamer suggested integrating the bulleted text into the summary. She commented on the need to ensure consistency when referring to a rating, pointing out that one of the bullet points included two different ratings. Dr. Boyd had written the bulleted text and agreed. He added that there may be other important issues outside the scope of those three categories and suggested inserting additional text to capture these issues. Dr. Swackhamer thought it would be better to keep it shorter as this is a mid-cycle review and not a full program review. Dr. Van Der Kraak said he was not sure that

the current text answered the key question, "Is the Program addressing the appropriate science questions?" In his view, the Program is addressing the right scientific questions. Dr. Swackhamer agreed, saying she thought this should be articulated in the text. She asked Dr. Van Der Kraak if he thought the expanded response should remain in this section. He thought that it should remain because it really adds to the more general response and gives it more weight. Dr. Swackhamer agreed to leave it in. Dr. Boyd offered to be responsible for revising the response to Charge Question 5.

Next Steps

Dr. Swackhamer summarized the section assignments:

- ✧ Dr. Swackhamer – Introduction and Charge Questions 2, 3, and 4
- ✧ Dr. Boyd – Charge Question 5
- ✧ Dr. Van Der Kraak – Charge Question 1

Ms. Drumm asked the Subcommittee members to e-mail their revised sections to Dr. Swackhamer (and copy her) by Monday, October 29. The sections will be compiled and the document will be sent out before the next call on November 6, 2007, from 1:00 p.m. to 3:00 p.m., Eastern Time. Dr. Swackhamer noted that editorial comments can be made through e-mail; this will help ensure that there is adequate time to discuss technical issues on the next call. Dr. Swackhamer added that Ms. Drumm should be copied on all e-mails, including those with editorial comments.

Closing Remarks

Dr. Swackhamer asked Dr. Francis if there was anything she wanted to add. She did not have anything to add, but she commended the Subcommittee members for their hard work; she and the other Program leaders were looking forward to seeing their recommendations. Dr. Swackhamer thanked Dr. Francis and her team for all the hard work they put into the review.

Dr. Swackhamer asked if there were any final comments or questions. There were none. Dr. Swackhamer thanked everyone for their comments and adjourned the call at 5:00 p.m.

Action Items

- ✧ Ms. Drumm will send a copy of the Subcommittee's draft report to Mr. Sarvana.

- ✧ Ms. Drumm will send the link to the BOSC Web Site to the Subcommittee members.

- ✧ Dr. Boyd will draft text describing what is missing from the Program in terms of risk management and send it to Dr. Swackhamer for inclusion in the response to Charge Question 1.

- ✧ Dr. Van Der Kraak will review Dr. Swackhamer's draft response to Charge Question 4.

- ✧ The Subcommittee members will send their assigned sections (copying Ms. Drumm) to Dr. Swackhamer by Monday, October 29, 2007.

- ✧ The next conference call is scheduled for November 6, 2007, from 1:00 p.m. to 3:00 p.m., Eastern Time.

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B·O·S·C

BOARD OF SCIENTIFIC COUNSELORS

EDC MID-CYCLE SUBCOMMITTEE

AGENDA
October 17, 2007
3:00 pm – 5:00 pm Eastern Time

Participation by Teleconference Only
866-299-3188
code: 2025648239#

3:00-3:05 p.m.	Welcome	Dr. Deborah Swackhamer Subcommittee Chair
3:05-3:10 p.m.	Administrative Procedures	Heather Drumm Subcommittee DFO
3:10-4:00 p.m.	Subcommittee Discussion - Draft Report	Dr. Deborah Swackhamer Subcommittee Chair
4:00-4:05 p.m.	Public Comment	
4:05-5:00 p.m.	Subcommittee Discussion, continued - Draft Report - Next Steps	Dr. Deborah Swackhamer Subcommittee Chair
5:00 p.m.	Adjourn	